

June 2010 Select Agent Workshop

Agricultural Select Agent Program, APHIS USDA

CDC Select Agent Program, CDC HHS

Bioterrorism Risk Assessment Group, CJIS FBI



Workshop Agenda

7:30–8:15	Registration
8:15–8:30	Select Agent Directors’ Welcome Remarks Directors: Mike Firko (APHIS-PPQ), Freeda Isaac (APHIS-VS), Rob Weyant (CDC)
8:30–9:30	Current Topics regarding the Select Agent Program – Mike Firko, Freeda Isaac, Rob Weyant
9:30–10:30	Inspection Trends; Best Practices for Preventing Occupational Exposures and Biocontainment Breaches – Charles Divan, Marsha Ray, Richard Henkel
10:30–10:45	BREAK
10:45–11:45	Discussion Panel # 1
11:45–1:00	LUNCH BREAK
1:00–2:00	Security for Select Agents – John Holcomb, Liz Snyder
2:00–2:10	BREAK
2:10–2:55	Security Risk Assessments: Overview, FBI Updates, Visitor Movement – Sherylyn Roberson, Lori Bane, John Strovers
2:55–3:00	BREAK
3:00–3:45	Discussion Panel # 2
3:45–4:00	Closing Remarks and Introduction to Breakout Sessions – Tru Twedt
4:00–6:00	Breakout Sessions: APHIS/CDC Form 1, Form 2, Form 3, Forms 4&5, CJIS FD-961 Form, DHS National Infrastructure Protection Program

Welcome!

8:15-8:30



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Current Topics regarding the Select Agent Program

8:30-9:30



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External Reports on the Federal Select Agent Program, and Responses by APHIS/CDC

Michael Firko, Ph.D.

Director, Agricultural Select Agent Program, Plants
Animal and Plant Health Inspection Service
U. S. Department of Agriculture



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During 2009, there were five reports on the Federal Select Agent Program

- National Academy of Sciences
- National Science Advisory Board for Biosecurity
- Working Group on Strengthening the Biosecurity of the United States (Executive Order 13486)
- Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight
- Defense Science Board



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National Academy of Sciences

“Responsible Research with Biological Select Agents and Toxins”

Nine recommendations, including:

“The list of select agents and toxins should be stratified in risk groups according to the potential use of the material as a biothreat agent” with associated threat-based security requirements.



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National Science Advisory Board for Biosecurity

“Enhancing Personnel Reliability Among Individuals with Access to Select Agents”

Five recommendations including:

- It is appropriate to enhance extant personnel reliability measures, but the promulgation of a formal, national Personnel Reliability Program is unnecessary at this time.
- The list of select agents and toxins should be reduced or stratified



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Working Group on Strengthening the Biosecurity of the United States

(Executive Order 13486)

“Report of the Working Group...”

Four recommendations including:

- Select Agent Regulations. ...consider the development of a stratification scheme that includes biodefense and biosecurity criteria ... so that security measures may be implemented based on risk
- Personnel Security. Enhance the SRA at the Federal level to allow for improved vetting of U.S. citizens and foreign nationals
- ... minimum set or prescriptive security standards...



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Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

“Report of the Trans-Federal...”

Sixteen recommendations, including:

- Identify or establish a Federal entity to coordinate biosafety and biocontainment oversight activities, and to ensure comprehensive and effective Federal oversight for all high and maximum containment research facilities and activities in all sectors
- Develop a registry of all high and maximum containment facilities in the United States



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Defense Science Board

“Report on the Department of Defense Biological Safety and Security Program”

NOTE: The DoD system was examined for potential best practices

Seven recommendations, including:

- Examine “isolation” of computer systems
- Maintain personnel reliability program... balance risk of malevolent insider against detriment to the laboratory mission



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Interagency Deliberations

Immediately following release of these reports the White House National Security Council convened an interagency working group to discuss the Executive Branch response to the reports



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Collective Findings

- BSAT research is essential to national security
- BSAT need to be secured
- Need for security needs to be balanced with need for research
- There is a lack of specific, risk-based security measures in the regulations
- Oversight by multiple, non-regulatory bodies complicates compliance, and may be a disincentive
- These issues need to be addressed



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Actions: Explore Tiering BSAT List

In the interests of securing BSAT appropriate to their level of risk, explore:

- Designating a subset of BSAT as “Tier 1”
- Regulatory options for graded protection
- Reducing the overall number of agents on the BSAT list



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Actions: Explore Creation of an Interagency BSAT Advisory Board

The Board could provide recommendations on:

- Possible tiering and Reduction of the BSAT list
- Establishment of graded security for different BSAT
- Coordinated and reciprocal inspection
- Interagency cooperation on resolution of compliance issues
- Information sharing among agencies



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Biennial Review of the List of Select Agents

Freeda Isaac, DVM

Director, Agricultural Select Agent Program, Animals
Animal and Plant Health Inspection Service
U. S. Department of Agriculture



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Biennial Review of the List of Select Agents

- Mandated by statute, Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Section 351A(a)(2) and Section 212(a)(2)
- Review of list every 2 years
- Last change to the list of select agents was published in October 2008



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Biennial Review of the List of Select Agents

- Technical Review committees of Subject Matter Experts
- Federal scientific experts evaluate agents based on certain criteria



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Biennial Review of the List of Select Agents

- Criteria for evaluation of agents
 - Effect on human, animal or plant health of exposure to the agent or toxin
 - Degree of contagiousness of the agents or toxins and the methods by which the agent or toxin is transferred to humans,
 - Availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin,



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Biennial Review of the List of Select Agents

- Any other criteria the Secretary considers appropriate
- Examples: Use in bioterrorist event, ability to immunize/treat, ease of dissemination, ease of production, environmental stability, transmissibility of agent or toxin, morbidity or mortality rate, etc.



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Biennial Review of the List of Select Agents

- Opportunities for Public Comment
 - Advanced Notice of Proposed Rulemaking (ANPR) and Proposed Rule
 - Outlines action agency is contemplating
 - Asks questions of the public to inform the process
 - Public can provide written comments to the answers and proposed actions
 - Usually 60 day comment period
 - All comments are reviewed and agency can adjust actions as needed
 - All comments addressed in preamble when proposed or final rule is published



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National Select Agent Workshop: Update on Recent Initiatives

Rob Weyant, PhD

Director, Division of Select Agents & Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control & Prevention



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Recent Initiatives

- Information Sharing with State Preparedness Partners
- Enhanced Monitoring of Select Agent Transfers
- National Select Agent Hotline
- New Entity Orientation Project



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Protocol for Information Sharing with States: Security Requirements

- Plan for the Use of this Information
- Policies/Procedures for Safeguarding Information from Unauthorized Access or Release
- Designated Custodian for Information and Agreement to Limit Sharing
- Opinion from State Legal Council on Protection of Information from Release Under Open Records Laws



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Protocol for information Sharing with States: Types of Information Shared

- Name and Location of CDC-Registered Entities in Jurisdiction
- Name and Contact Information for Responsible Officials at these Entities

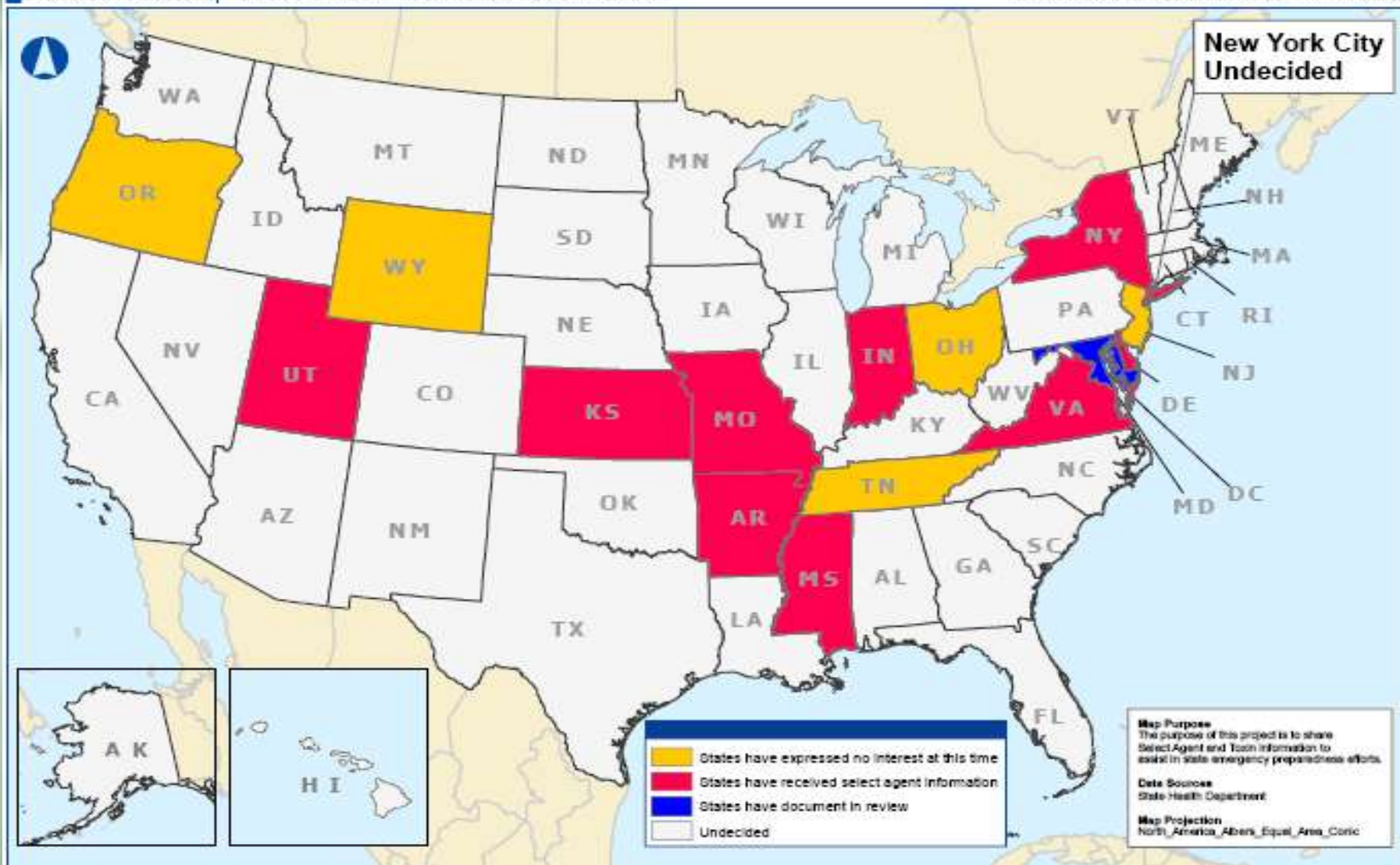


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Sharing Select Agent and Toxin Information with the States

The purpose of this project is to share Select Agent and Toxin information to assist in state emergency preparedness efforts.



National Select Agent Whistleblower Hotline

- **Anonymous Reporting**
 - Confidential way to report safety and security issues
 - Report must indicate it is a “Select Agent Program” issue
 - Monitored by the Department of Health & Human Services, Office of Inspector General (OIG)
 - Hotline information:
 - ★ <http://www.selectagents.gov>
 - ★ <http://oig.hhs.gov/fraud/hotline>



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National Select Agent Whistleblower Hotline

- **OIG Hotline contact information:**
 - Voice: 1-800-HHS-TIPS (800-447-8477)
 - Fax: 1-800-223-8164
 - Email: HHSTips@oig.hhs.gov
 - Mail: Office of Inspector General
- Department of Health & Human Services
- Attn: Hotline
- P.O. Box 23489
- Washington, DC 20026



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Pilot Project: Improved Tracking of Select Agent Shipments

- Partnership with FedEx to ensure packages containing select agents and toxins are tracked during transit:
 - DSAT notifies FedEx prior to shipment of the FedEx tracking information for select agent packages
 - FedEx notifies DSAT of any issues that may occur during transit of package (e.g., truck accident, weather delays)
 - DSAT notifies FedEx of select agent packages not received (e.g., overnight delivery not received next day).
 - ★ FedEx will be notified to determine location of package
 - ★ FBI will be notified if FedEx is unable to locate package



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Improved Tracking of Select Agent Shipments: Status Report

- 33 select agent packages have been tracked thus far
- Success stories:
 - FedEx notified DSAT that a select agent shipment was not accepted at the origin location and was returned to sender via another FedEx tracking number. Shipment was rejected due to a discrepancy in the amount of dry ice in the box vs. the amount listed on the shipping labels. DSAT was able to contact the sending entity to notify them of the situation.
 - A select agent shipment was not received in the expected time frame, and FedEx was able to locate the package overseas (held up due to workers' strike).



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Entity Assistance Program

Assistance for the

- organization planning to possess, use and transfer select agents and toxins,
- organizations considering select agent registration,
- newly appointed Responsible Officials,



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Entity Assistance Program: Assistance Provided

- Requirements for Registration
- Requirements for maintaining Registration
- Consultation on documentation required
- Consultation on Responsible Official responsibilities



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Requesting Assistance

Submit and e-mail request to

LRSAT@cdc.gov

Subject: “Entity Assistance Program”

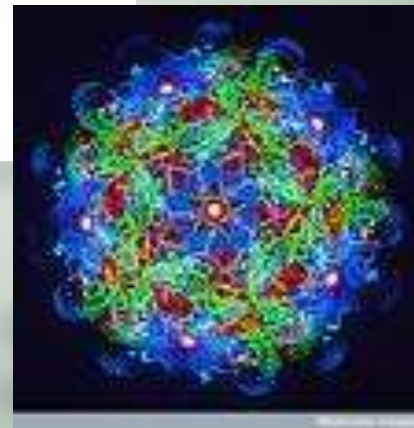
Provide contact name, organization, and telephone number



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Thank You



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Inspection Trends; Best Practices for Preventing Occupational Exposures and Biocontainment Breaches

8:30-9:30



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Common Issues Observed During Agricultural Select Agent Program Inspections

Charles L. Divan
Branch Chief
Agricultural Select Agent Program



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Overview

- Plans (Biosafety, Security, Incident Response)
- Drills (Biosafety, Security, Incident Response)
- Inventory and Record Keeping
- Training (General and Agent Specific)



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Biosafety (Biocontainment) Plan

- Lab Safety
 - Sharps, Glassware, Needles
 - Aerosol and Splashes
 - Decontamination of cultures and stocks
 - Goggles and Gloves
 - Carpets, Rugs, Cloth Chairs



Security Plan

- Include information for safeguarding agents and toxins
 - Theft
 - Loss
 - Release
- Access control for routine cleaning, maintenance and repairs
- Opening suspicious packages
- Intra-entity Transfer Protocol



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Incident Response Plan

- Must include contact information
- Personal Roles and line of communication-phone tree
- Emergency medical information and first aid
- List of PPE-type and location
- Procedures for emergency evacuation
- Site security and control



Drills

- Tabletop
 - Quiz
 - Discussion
 - Scenario
- Practical exercises
 - Spilled Agent
 - Unauthorized access
 - Medical Attention
 - Biocontainment Breach



Inventory and Record Keeping

- Current, accurate inventory for each select agent and toxin
 - Name and characteristics
 - Quantity
 - Purpose
 - Location (box and position)
- Removal from storage- **full name, no initials/nick name**
- Controlled Access- **no piggy-backing**



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General Training

- Biosafety and biosecurity training must be given to everyone who is SRA approved and to Non-SRA approved individuals such as visitors.
- Refresher training must be given annually
- Testing of knowledge to verify understanding of material
- Record of attendance- name, date, description of training – signatures (**no initials**)



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Agent Specific Training Workers and Visitors

- Agents and toxins presently in lab
- Agents and toxins registered but not present
- Testing of knowledge to verify understanding of material
- Record of attendance- name, date, description of training, signature **(no initials)**



Resources

- <http://www.selectagents.gov/>
 - <http://www.selectagents.gov/Checklists.html>
 - <http://www.selectagents.gov/Resources.html>



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Questions



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Inspection Trends

Marsha Ray, MS
Division of Select Agents and Toxins



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Authority to Inspect (42 CFR 73.18)

- “Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.”
 - Inspections may be announced or unannounced



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Reasons for Inspections

- Renewal of certificate of registration;
- New application;
- Verification of corrective action taken;
- Evaluation of new space (commissioning documents);
- Compliance issue;
- Theft, loss, or release;
- Joint inspections with APHIS (HHS-only; USDA-only)

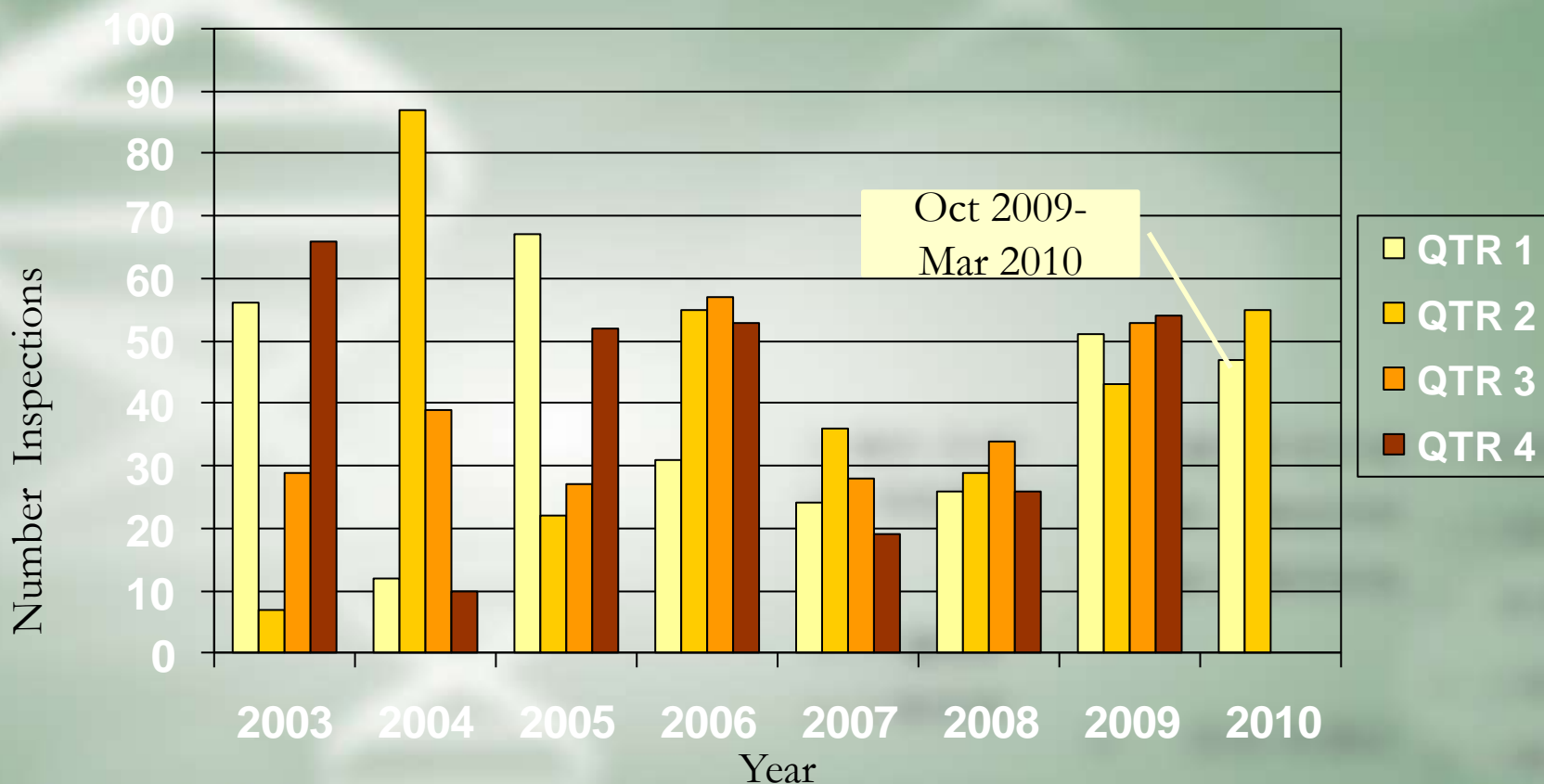


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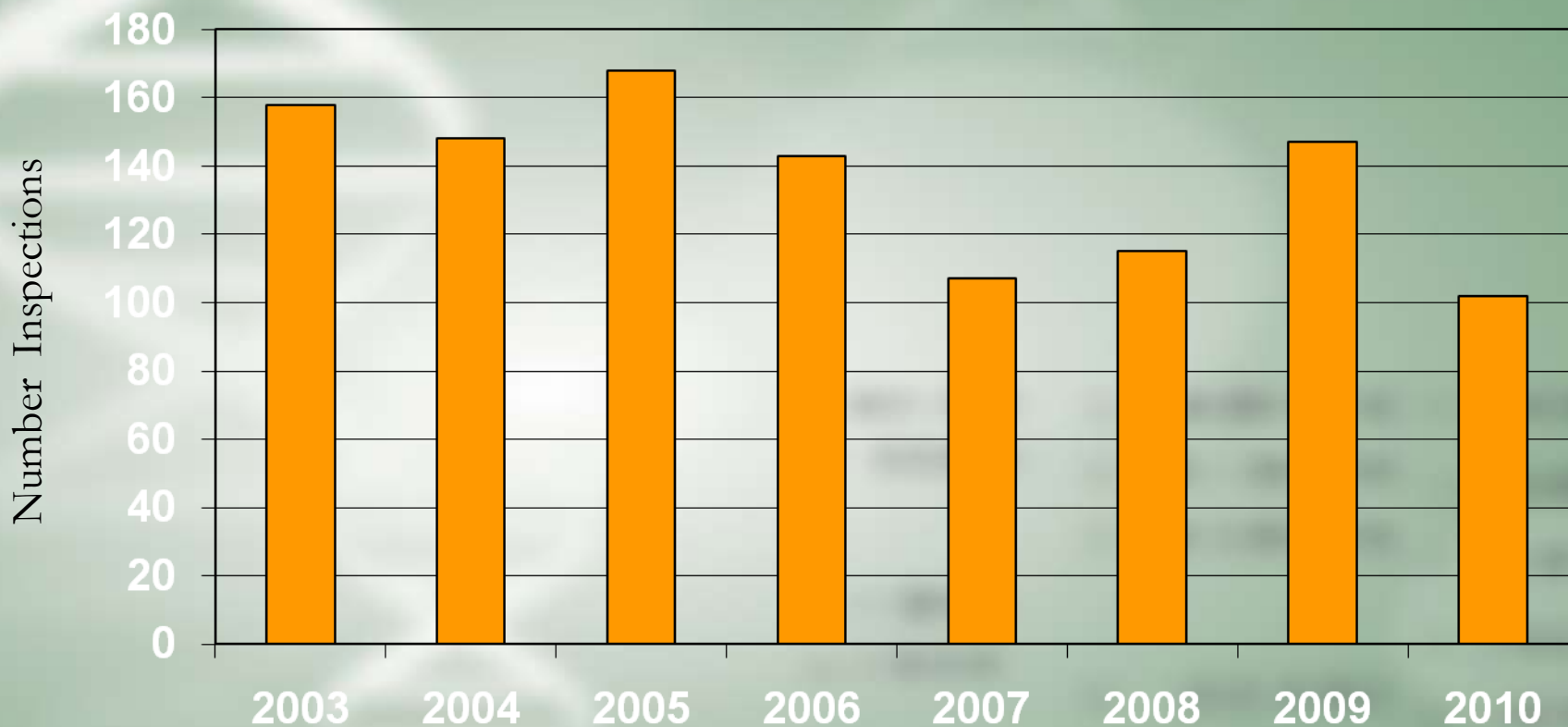
CDC Inspections Conducted by Quarter and by Fiscal Year

(As of 03/31/2010)



CDC Select Agent Inspections Conducted by Fiscal Year

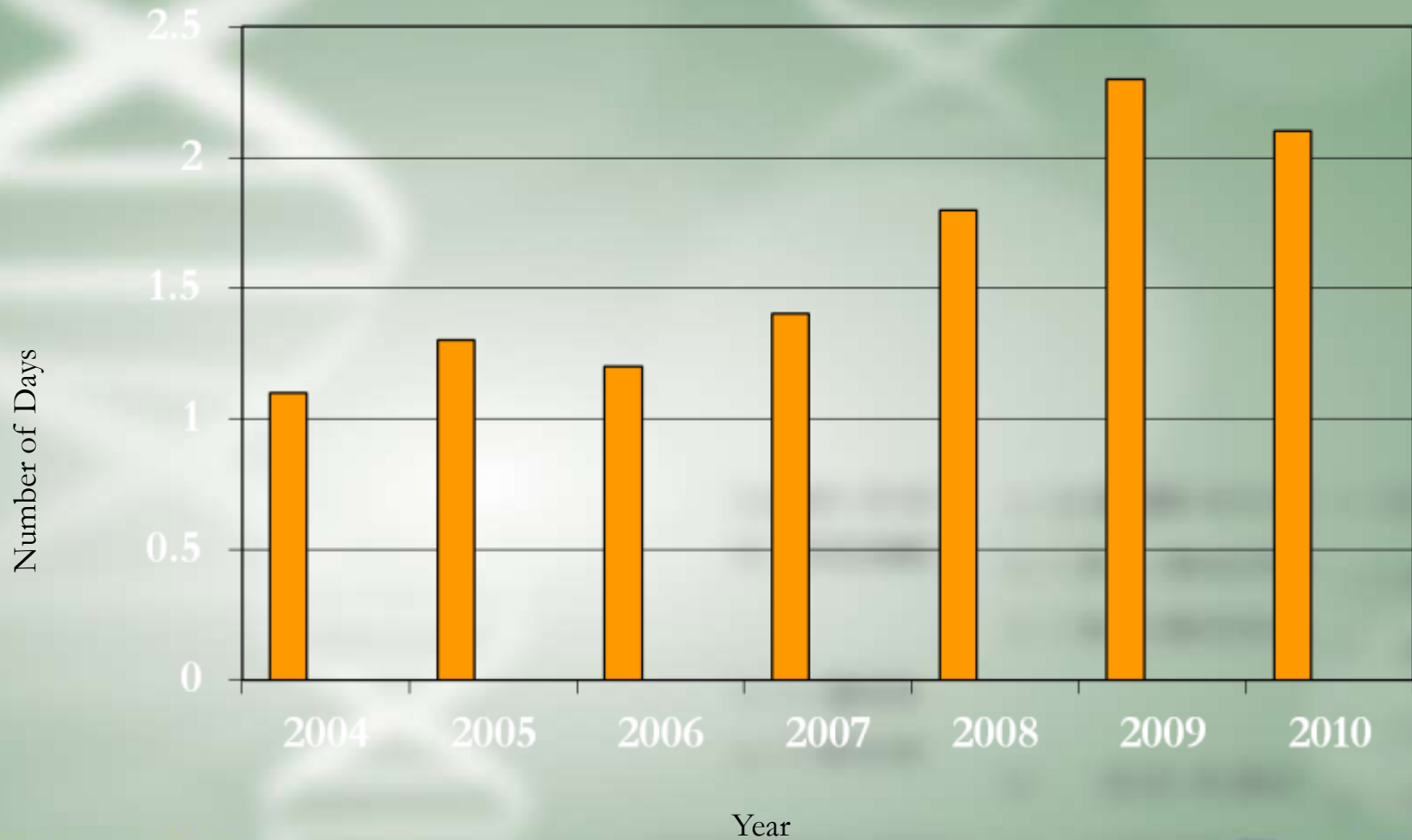
(Total=1037; As of 03/31/2010)



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Average Number of Days per Inspection 2004-2010



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INSPECTION PROCESS



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CDC Inspection Process

- Opening Introduction
- Tour facility
 - Registered laboratories and storage rooms
 - HVAC
 - Overall physical security
 - Security facilities
 - Shipping and receiving



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CDC Inspection Process (Continued)

- Review of documents
 - Plans: biosafety, incident response, and security
 - Annual Drills/exercises
 - Training: safety, security, risks (SRA approved & visitors);
 - Annual inspections
 - Access records (electronic and manual)
 - Transfers (Form 2); TLR (Form 3); Identification of SA from diagnostic specimens (Form 4); Intra-entity
 - Inventory records



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CDC Inspection Process (Continued)

- Review of documents
 - Verification of accuracy of records and databases
 - Biosafety cabinet certification
 - Fume hood certification, if applicable
 - Verification of facility design and operational parameters
 - HEPA filter certification, if applicable
 - Discrepancy and incident reports
 - IBC and IACUC minutes, as appropriate



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CDC Inspection Process (Continued)

- Review of documents
 - Medical surveillance
 - Chemical Hygiene Plan (if applicable)
 - Pest management
 - Shipping/receiving protocols
 - Other documents, as appropriate
- Interviews
- Debriefing



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CHANGES/IMPROVEMENTS



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Improvements to CDC Inspections

Checking Inventory

Conducting Interviews

More thorough review of documents

More thorough review of facilities

Checking HVAC Systems

Checking Security Systems

“Expect inspections to be more comprehensive”

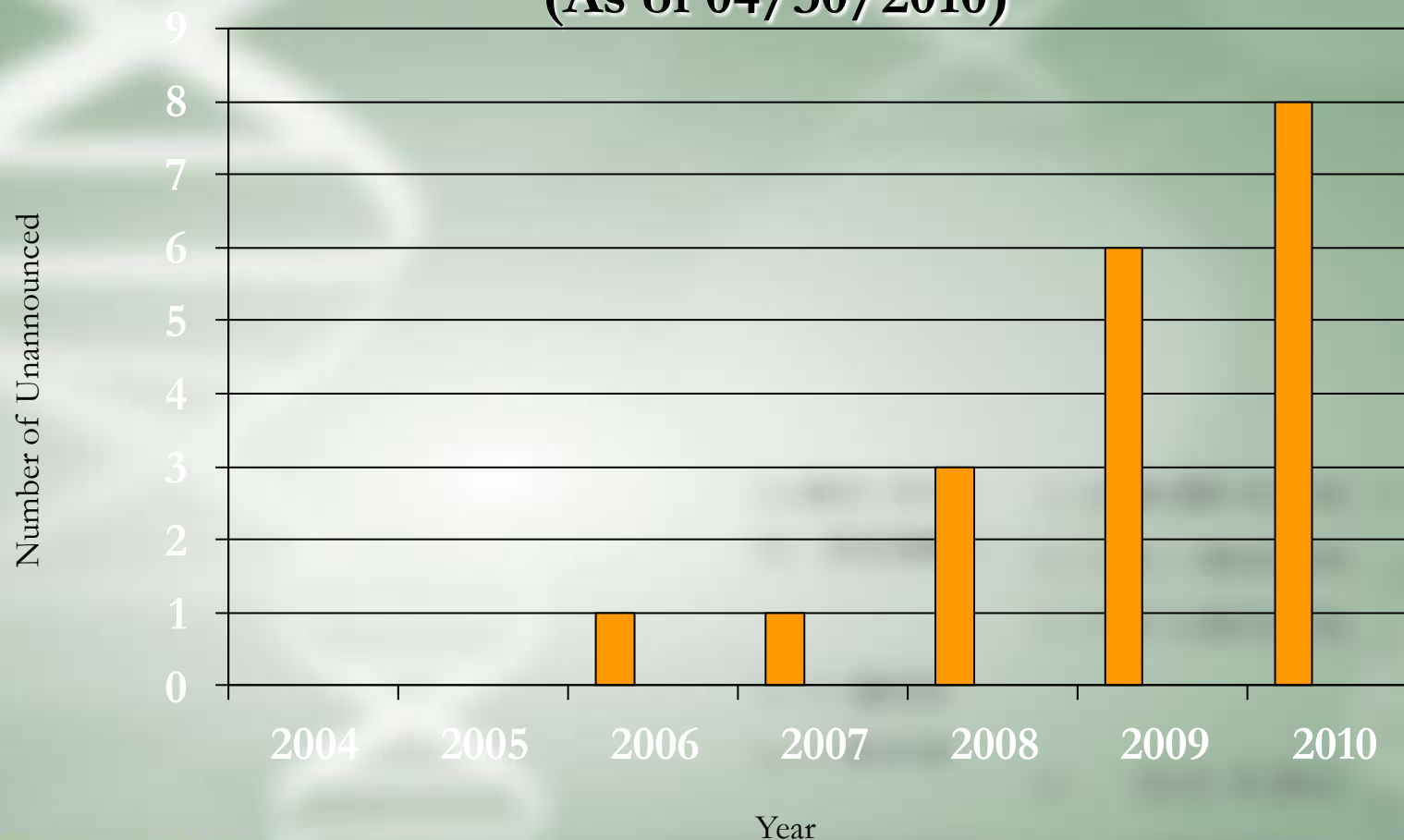


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Number of Unannounced CDC-Led Inspections Calendar Year 2004-2010

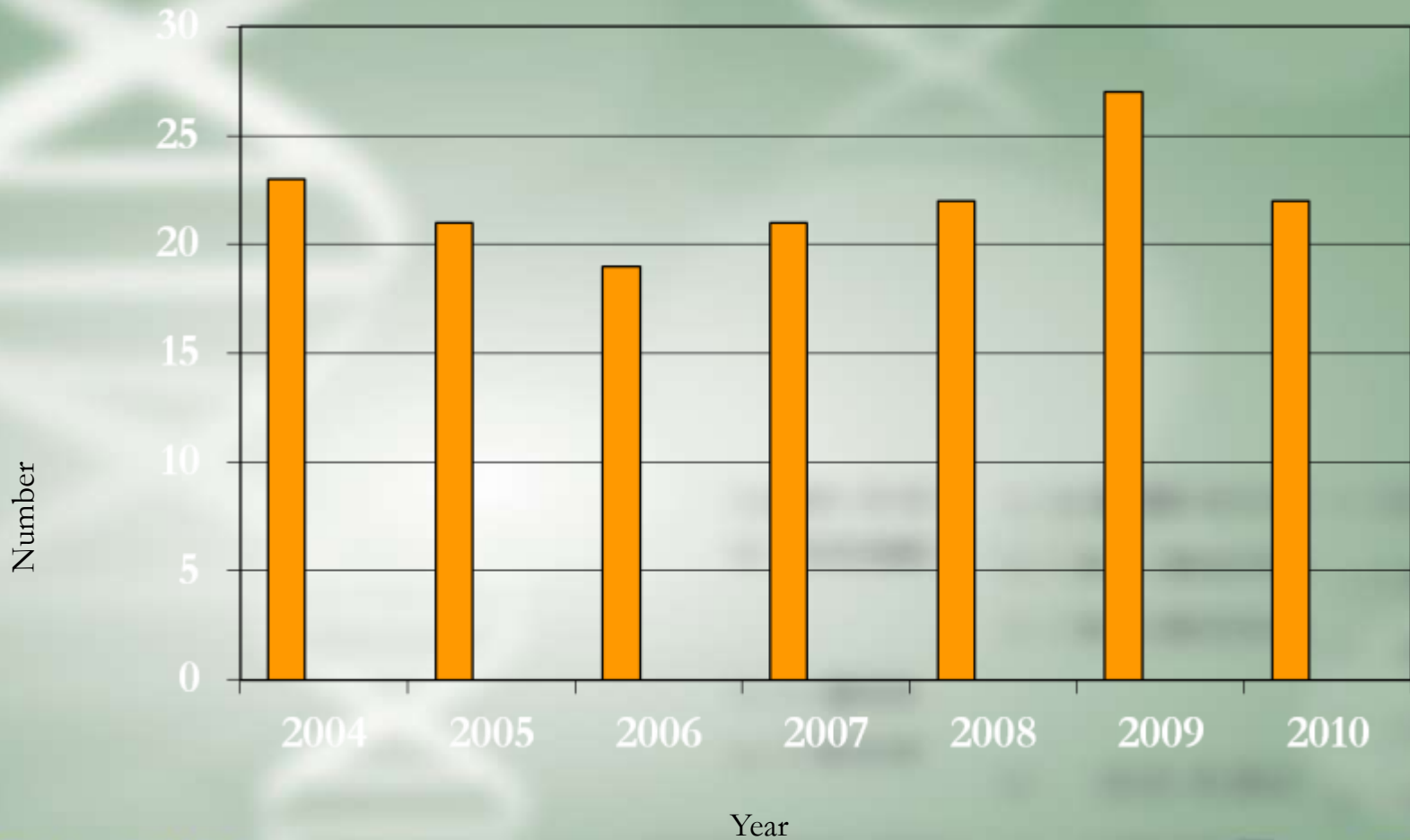
(As of 04/30/2010)



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Number of Citations per Inspection 2005-2009



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Frequent Citations

CDC Inspections

73.14(b) Incident Response Plan

Response procedures for theft, loss, or release, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc.

The response procedures must account for **hazards** associated with the select agent and toxins and appropriate actions to contain such select agent or toxin.



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Frequent Citations

CDC Inspections

73.15(a) , (b), and (c) Training

- Biosafety and security training – individuals approved for access and visitors
- Address the needs of the individual, the work they will do, and the risks posed by the select agents or toxins
- Annual refresher training
- Record of training – name, date, description of training, means used to verify understanding



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Frequent Citations

CDC Inspections

73.12(d) Review of Biosafety Plan annually;

Annual Drills/Exercises

73.11(f) Review of Security Plan annually;

Annual Drills/Exercises

73.14(d) Review of Incident Response Plan
annually; Annual Drills/ Exercises



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Frequent Citations

CDC Inspections

73.9(c) Annual Inspections

- The Responsible Official must ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part.
- Results must be documented, and any deficiencies identified during an inspection must be corrected.



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Frequent Citations

CDC Inspections

- 73.12(b)/BMBL D15: Annual verification of facilities design and operational parameters
- 73.12(b)/BMBL D14: Annual certification of HEPA filters and housing
- 73.12 (b)/BMBL D9: Under failure conditions airflow will not be reversed



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INTERESTING FACTS



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Interesting Facts, CDC Inspections 2006 - 2009

73.11(d)(1) – Unauthorized access

2006 = 0; 2009 = 36

73.17(a)(1) – Accurate & Current Inventory

2006 = 9; 2009 = 23

73.9(a)(4) – RO ensures compliance

2006 = 0; 2009 = 10



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Interesting Facts, CDC Inspections 2006 - 2009

BMBL (BSL3), D15 – Annual Verification

2006 = 14; 2009 = 49

BMBL (BSL3), Reversal of Airflow; HEPA-filter
Leak testing, D9

2006 – 3; 2009 - 35

(Note: Changes in language, BMBL 4th ed. and 5th ed.)



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Inspection Tips for the RO

- If you state something has been done in your response to an inspection deficiency, be sure that it has been done
- Complete annual requirements each year
- Make the plans specific to your entity
- Conduct drills that test the plans
- Devise systems to ensure accuracy of records
- Devise systems to ensure accuracy of inventory
- Ensure that training has been effective



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Best Practices for Preventing Occupational Exposures and Biocontainment Breaches

Richard Henkel, Ph.D.

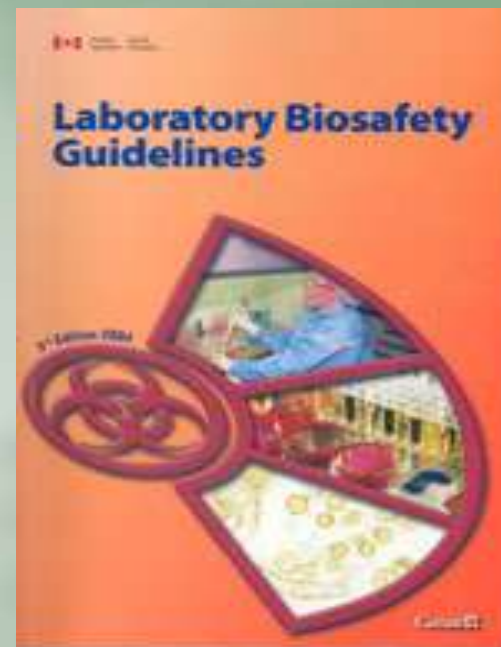
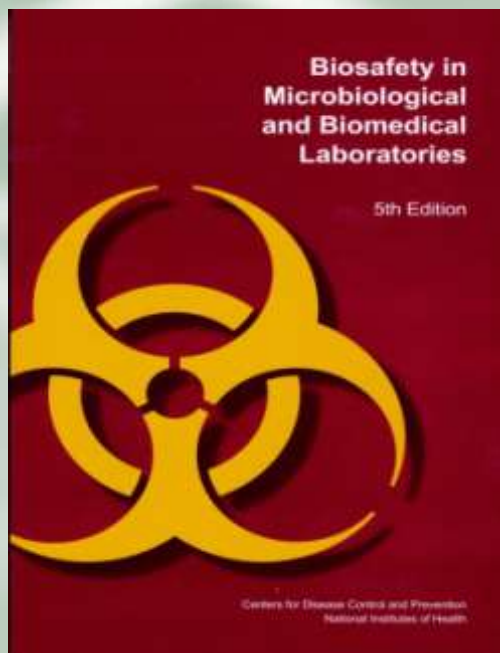
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins



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Biosafety Guidelines and Codes of Practice*



*BMBL is both a code of practice and an authoritative reference.



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“Stuff Happens”



Why worry about potential exposures?

- 43 CFR 73.19 (b) “Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.”
- There were no distinguishable accidents or exposure events identified in more than 80% of the >4000 LAIs reported before 1978. Studies did show that in many cases the infected person worked with a microbiological agent or was in the vicinity of another person who was handling an agent.

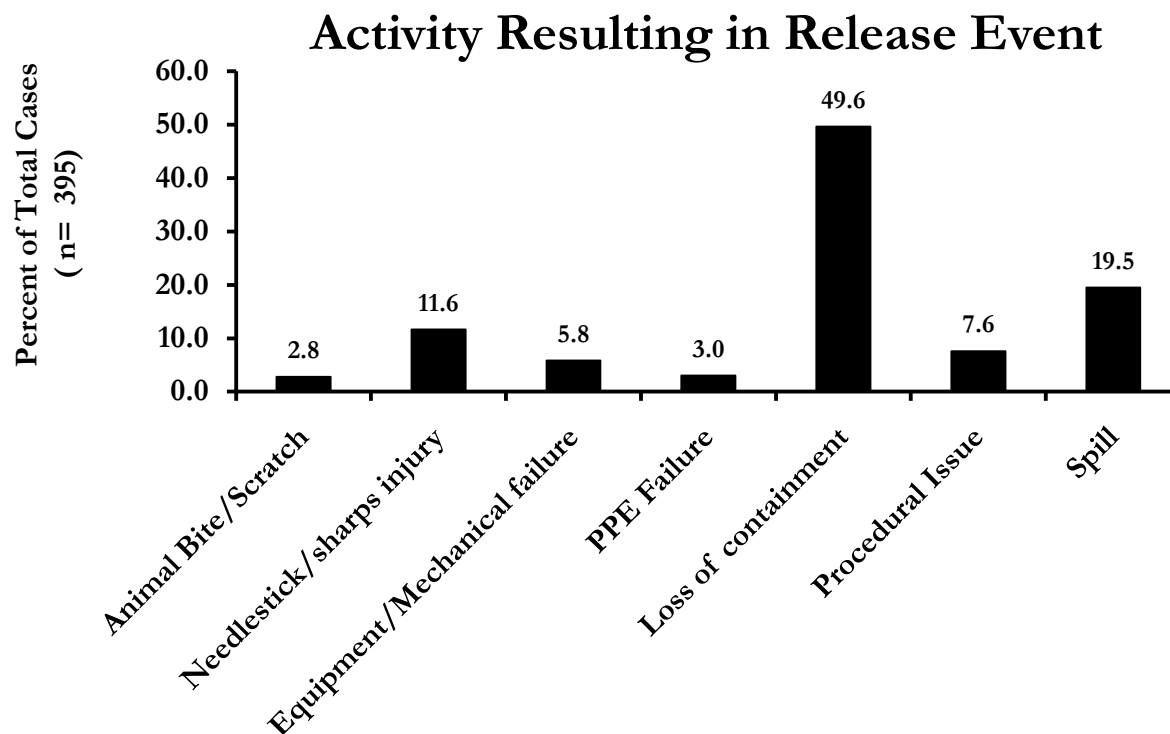
*Pike RM. Laboratory-associated infections: incidence, fatalities, causes, and prevention. Annu Rev Microbiol. 1979;33:41-66.



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Potential Select Agent Releases Reported to CDC 2003-2009



Case Studies of Biocontainment Breaches (Releases) Involving Select Agents & Toxins



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Case Study #1

Potential Occupational Exposure to *Brucella melitensis* in a Clinical Laboratory



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2010 Clinical Laboratory *Brucella* Exposure

- DSAT forwarded Form 3 report information to the Bacterial Special Pathogens Branch (BSPB) in the Division of High-Consequence Pathogens and Pathology at CDC, stating 32 laboratorians were potentially exposed to an unspciated *Brucella* specimen.
- Primary case patient was the son of another brucellosis patient from April 2010; both mother and son traveled to Mexico where they consumed goat cheese in December 2009.
- BSPB epidemiologists contacted state DOH, provided medical surveillance recommendations and laboratory support.
- BSPB identified isolate as *B. melitensis*.
- Provided medical countermeasure recommendations and BMAT testing.



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Laboratory Exposure Risks

4 labs manipulated the specimens resulting in 4 exposure incidents

1. FLOW CYTOMETRY LAB: **4 techs** poured lavender top tubes, mixed with lysing agent, performed washing steps, and performed centrifugation/vortexing on an open bench.
2. MICROBIO LAB: **32 laboratorians** potentially exposed – cultures were manipulated on an open bench
3. CYTOGENETICS LAB: cultivated bone marrow into RPMI (enhanced with serum) on an open bench; **1 tech**
4. HEMATOLOGY LAB: Opened cap on tube (on open bench) to make slide; **1 tech**

The final number of persons exposed is still being determined since additional people had walked in and out of labs during possible aerosolization.



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Deja Vu

- In 2010, as many as 54 persons were potentially exposed to *Brucella melitensis* after the specimen was handled outside of primary containment.
- In 1991, eight LAIs were reported* in a clinical microbiology lab after a worker exposed 31 co-workers to *Brucella melitensis* while working with the agent outside of primary containment.

*Staskiewicz J, Lewis CM, Colville J, et al. Outbreak of *Brucella melitensis* among microbiology laboratory workers in a community hospital. J Clin Microbiol. 1991;29:287-90.



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1991 Outcome vs 2010 Outcome

FACTOR	1991	2010
Organism	<i>Brucella melitensis</i>	<i>Brucella melitensis</i>
Type of containment break	Open bench	Open bench
# of exposures	31	54
# of infections	8	0
Infection rate	~26%	0
Initial report	LAI	Release
Medical countermeasures	Treatment of cases	Post exposure prophylaxis

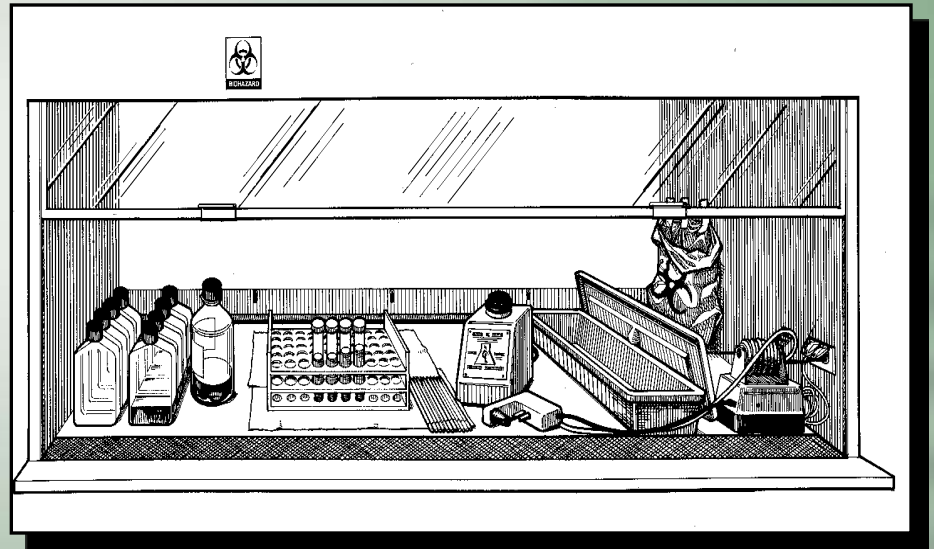


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Lessons Learned

1. The importance of primary containment
2. Reporting releases instead of LAIs
3. Availability of public health SMEs and resources
4. Importance of follow up



Case Study #2

Release of *Bacillus anthracis* in a Vivarium



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Incident Report

- A laboratory rabbit used for minor training procedures (blood collection and anesthesia administration) was noted to be lethargic, not eating and had lost approximately 15% of its body weight in the previous month.
- No gross lesions were observed except mediastinal lymph node enlargement. The animal was necropsied by two technicians who wore gloves but no other PPE during the procedure. Post necropsy analyses of specimens were sent to the state health department.
- The animal was housed in an 'clean' animal colony. The entity also conducted research with anthrax in a BSL3 research laboratory located in another section of the facility.



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The Diagnosis

- A diagnosis of anthrax associated with wild-type *B anthracis* was made.
- CDC BSPB was contacted through the CDC EOC to report a potential exposure to anthrax.
- Initial communications addressed post exposure prophylaxis strategies and exposure risk assessment.
- CDC DSAT was notified the following day and a conference call was conducted at approximately 11am.



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The Immediate Response

- Closure of all lab, animal and office rooms with potential involvement with index rabbit
- Closure of necropsy area at the Veterinary and Diagnostic unit
- Collection and safe storage of infected rabbit tissues, carcass and other materials
- Communication of decontamination plans to CDC DSAT



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CDC Team Deployment

- The most pressing concern expressed by the state DOH was whether there was any threat to the public health as a result of an aerosol release of anthrax.
- A decision was made to immediately send a team from CDC to investigate the incident.. The team left Atlanta 8 hours after the decision to deploy and arrived at approximately midnight.
- Team members included:
 - one Epidemic Intelligence Service Officer (MD/MPH) from BSPB,
 - two SRP veterinarians with extensive high containment laboratory experience,
 - one senior inspector from DSAT, and
 - one Biosafety Officer from DSAT .
- Logistical support for the deployed team was provided by the CDC Emergency Operations Center.



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The Investigation

- The investigation site visit began with an early morning meeting between entity officials, state DOH and the CDC investigation team.
- The meeting agenda addressed the purpose of the visit, the team member roles and the plan for the investigation.
- An update on the status of the facility including the decontamination process, ongoing operations and immediate actions, if any that needed to take place.
- No immediate concerns were conveyed to the team about the current status of the facility, operations or any employees.



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The Investigation

- Team members were assigned tasks based on subject matter expertise.
 - EIS Officer met with entity occupational health director , PI and other entity staff plus state DOH
 - DSAT inspectors and SRP veterinarians conducted an initial facility review and assessment
- SRP veterinarians reviewed animal health records, facilities, and procedures.
- DSAT inspectors conducted a thorough inspection of HVAC system, decontamination equipment and the containment barrier of the BSL3 laboratory.



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The Investigation

- CDC team met for a conference call with state DOH to discuss the preliminary findings.
- A consensus was reached that there was no credible evidence for an immediate threat to public health.
- CDC investigation continued on the second day with document reviews, interviews of staff and additional inspections of facilities.
- A close out de-briefing of entity officials was conducted with open and frank discussions of issues.



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Action Items

At the conclusion of the investigation, CDC Team recommended the following actions be taken:

- Initiate remedial actions including verification of decontamination of all rooms that may have been used to house the index rabbit.
- Institute vigorous decontamination procedures for all materials to be removed from the BSL3 laboratory,
- Continue to work closely with DOH on monitoring potentially exposed personnel,
- Conduct necropsies of remaining rabbits used for training procedures inside the BSL3 laboratory in the presence of a neutral observer,
- Transfer materials to CDC for testing.



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Follow Up

- Environmental tests conducted by entity and DOH were negative.
- All non-index rabbits tested negative.
- All pharmaceuticals used to treat index rabbit were negative.
- Initial MLVA results on the rabbit isolate showed that the isolate was closely related to the Ames strain. Since the lab uses variants of the Ames strain, these results are supportive of the hypothesis that the rabbit was infected with a lab strain
- The rabbit isolate matched 3 different toxin mutant strains used in the lab. Further PCR analysis indicated that the rabbit strain was a *lef* gene mutant which corresponded to the UTA 2 strain.



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Conclusions

- There was no credible explanation that could account for the transmission of anthrax to the rabbit found to be infected as a result of a major aerosol release.
- There was a plausible mechanism to account for transmission of the agent to the rabbit through improperly decontaminated equipment and/or reagents.
- The most likely cause of the infection was the inadequate decontamination procedures of equipment. A stainless steel rabbit restraint device used on animals in the BSL3 laboratory was also used in the BSL2 laboratory.
- The rabbit restraint device was removed from the BSL3 laboratory after chemical surface decontamination. An autoclave was available in the BSL3 laboratory for decontamination purposes, but it was not used to decontaminate the rabbit restraint device.



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Conclusions

- There was no evidence of any residual environmental contamination outside of the containment laboratory. All tests of environment were negative.
- In addition, extensive decontamination has been conducted of environmental surfaces in areas that may have been potentially contaminated by the infected rabbit.
- Based on these findings, there was unanimous agreement among team members that the public health threat was considered to be minimal.



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Conclusions

- Personnel present during the necropsy were not likely to have been exposed to anthrax spores, but to vegetative *B. anthracis*, requiring PEP of 10-14 days with ciprofloxacin or doxycycline.
- PEP with ciprofloxacin or doxycycline for 10-14 days was recommended for those persons identified as having worked in the same room as the index rabbit in the 10 days prior to its illness.
- For other potential local, limited aerosol exposures to anthrax spores, identified individuals taking PEP may be given information that would allow them to conduct symptom watches for inhalation anthrax for a total of 60 days from the closing for assessment and cleaning of the laboratories involved.
- There have been no reports of any human cases of anthrax related to this event.



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Conclusions

- After receiving verification that the animal husbandry room was properly decontaminated and assurance that all environmental test samples were negative, CDC DSAT agreed to permit the animal husbandry rooms to be returned to normal operating conditions.

and

- Additional restraining cages for exclusive use in the anthrax lab were purchased.



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Acknowledgements

Theresa Smith MD, MPH

Meredith G. Morrow, MSPH

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Nathanial Powell, DVM

Allison Williams, DVM

Marsha Ray

Thomas Miller

James Love and,

The unknown CDC Emergency Operations Center staff member who obtained airline tickets to get us home on the Wednesday night before Thanksgiving



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Break

10:30-10:45



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Discussion Panel

#1

10:45-11:45



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Lunch

11:45-1:00



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Security for Select Agents

1:00-2:00



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Security

John B. Holcomb

Security Specialist

Division of Select Agents and Toxins

Supervisory Special Agent Liz Snyder

Bioterrorism Risk Assessment Group

Criminal Justice Information Services Division

Federal Bureau of Investigation



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Agenda

- Security System Overview
- Risk Management
- Security System Design
- Security Plan
- Incident Response

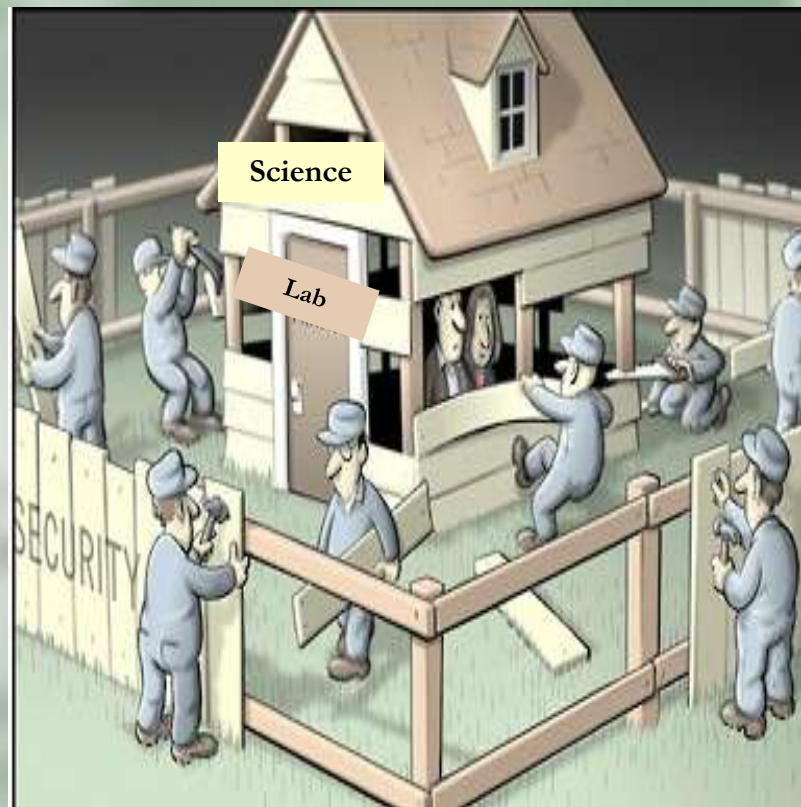


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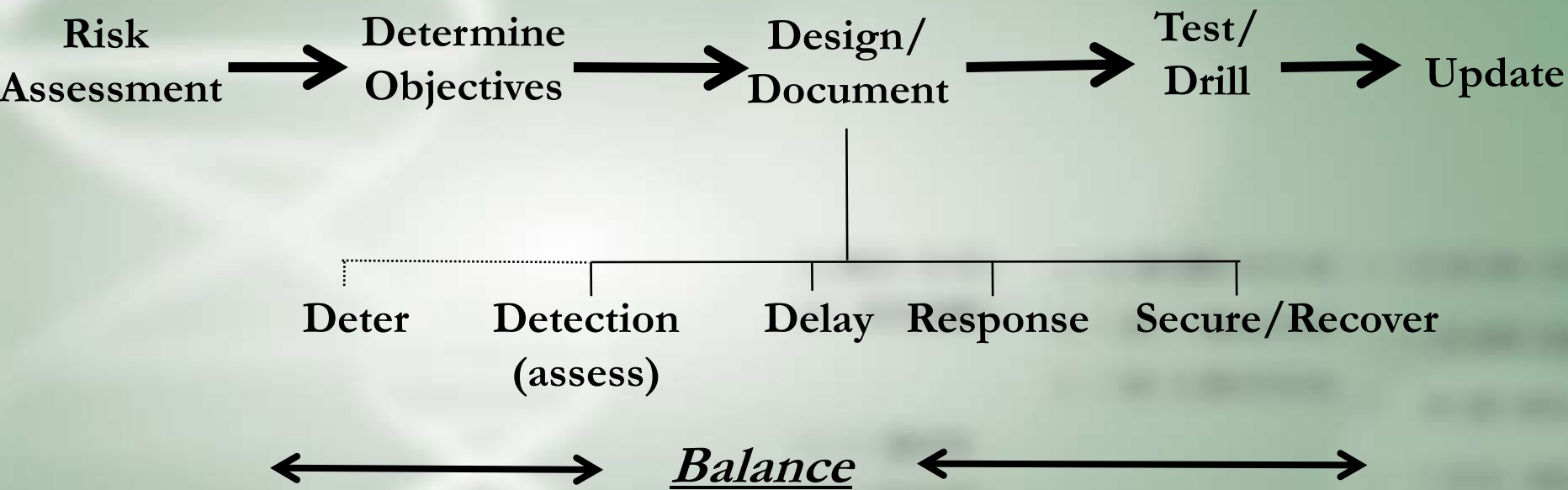
What we see in the field

- Security is very good
- Opportunities to save resources
 - Opportunity Costs
 - Dollar Costs
- Opportunities to focus



Security System Design and Assess

Not “a lock” but a system!



Site-specific Risk Assessment

- Risk Formulas

Risk= Likelihood of a bad thing happening

*Risk= Threat or Hazard * Vulnerabilities * Consequence*

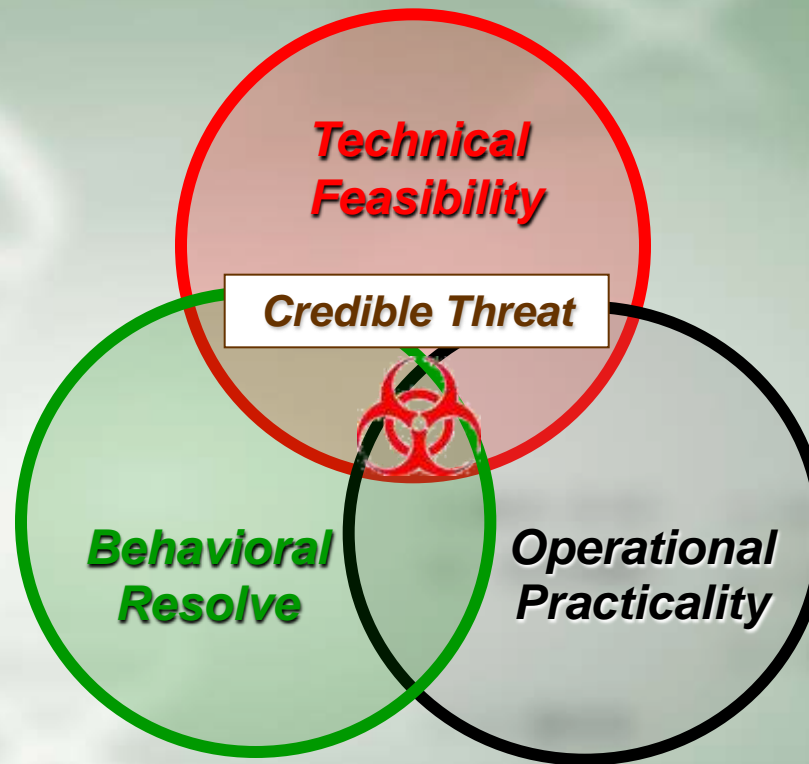
- **Vulnerabilities:** Weakness that can be exploited
- **Natural Hazards:** Harm or Difficulty from natural phenomena
- **Threats:** Credible adversary with intent and capability to access the select agent
- **Consequence:** Human, Economic, Psychological, Financial (cost of replacing the science)



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Threat Credibility



Threats

Law Enforcement Adversaries

Select Agent Interests

- **Criminal**
 - Lone wolf offenders; commonly little or no technical ability, motivation from monetary to political, operationally practical. Examples threats, violence, and theft.
- **Terrorism**
 - Lone wolf (radicalized) or state-sponsored. Some technical ability, politically, socially, and/or religiously motivated, operationally feasible.
- **Intelligence**
 - State-sponsored, information driven. Advanced technical ability. Motivation is political; operationally complicated, but **practiced**.



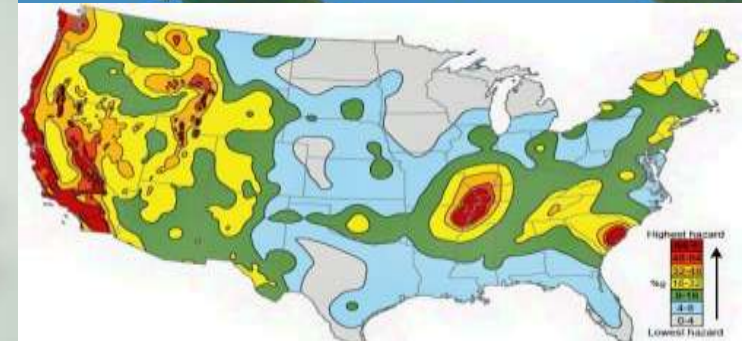
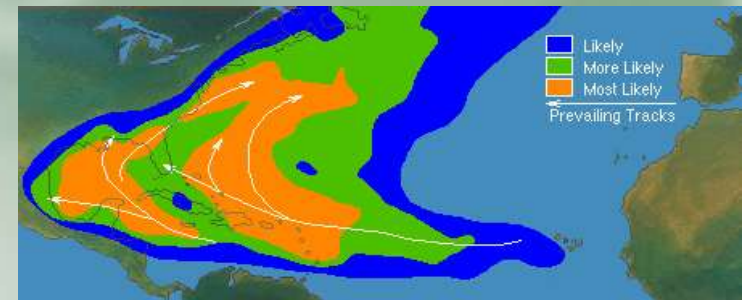
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Site-specific Risk Assessment

Natural Hazards

- Know your hazards based on your location
- Know what they will do to the inside of the facility (not just the building)
- Know what they will do to the entire entity
- Know the effects and effects of effects of the natural hazards



Site-specific Risk Assessment Vulnerability

- **Vulnerability Assessment** Determines weaknesses in the security system which exposes an agent to a threat
- **Scenarios** A technique
 - Game theory
 - Paths (optimal, all paths, realistic)
- **Common steps**
 - Ask 'what else would happen'
 - Threats Adversary, Tools and Organization
 - If possible, group them based on common attributes and requirements



Site-specific Risk Assessment Consequence

- Agent-specific **Consequence Assessment** determines human (mortality and morbidity), economic and psychological impacts of loss, theft or release of the agent in its current form based on its intended use). This should be done for each select agent or toxin.
- Entity core competency
- Other consequences Damage to your image, lawsuits, insurance rates



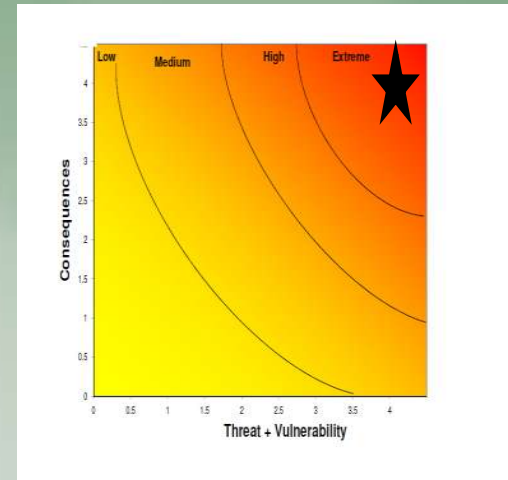
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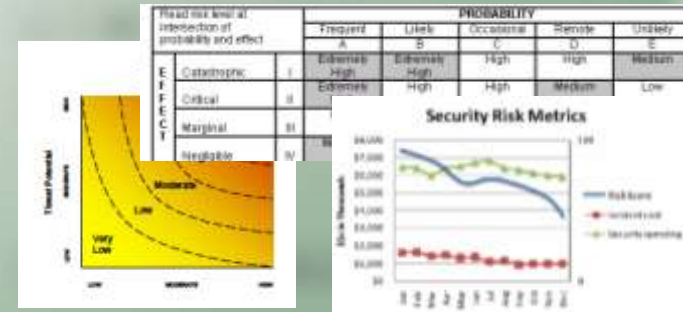
Site-specific Risk Assessment

Relate Probability to Hazard

- *Many different programs and methods*
- Must pass common sense test and relate to your site-specific environment
- Should relate consequence to likelihood (threat + vulnerability)
- Should be easy to understand
- Always ask 'why'



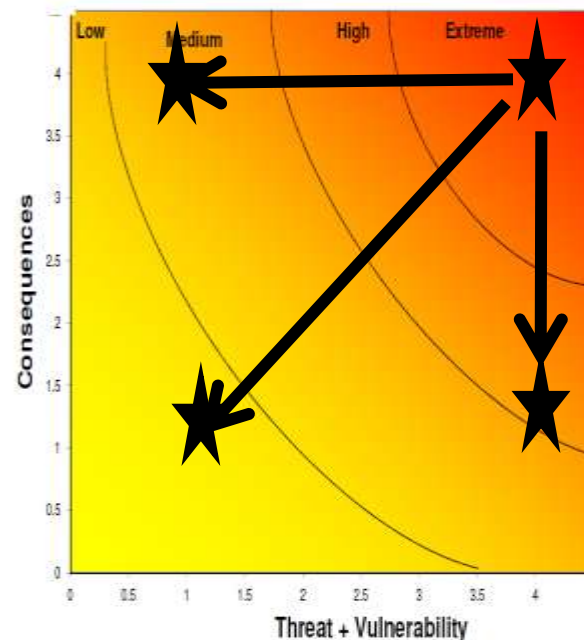
Many models



Site-specific Risk Assessment

Mitigate Risks

- **Mitigate Risks**
 - Decrease vulnerabilities
 - ★ Increase security
 - Decrease consequences
 - ★ Excluded Strain
 - Both
- **Transfer risk**
 - Move to a 'campus'
- **Avoid Risk (don't do it)**



One of many models

Security System Objectives

Prepare

- Well documented and understood operational processes
- Understanding of all the regulations that affect security
- Understanding of your personnel
- Understanding of the investigation's requirements
- Understanding the future (where will your entity be in 10 years?)



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Security System Objectives

Regulations/Rules that apply

- *Select Agents 7 CFR 331, 9 CFR Part 121 and 42 CFR 73*
- State Laws
- Local Ordinances
- Fire Codes/Building Codes
- American with Disabilities Act
- Safety Rules



Security System Objectives

Discuss

- **Involve all Stakeholders**
 - Security, Investigators, Facility Manager and Entity Leadership, possibly Legal and Local Government
- **Know** Consequence of agent in its current form (registered state, intended use)
- **Bring** Regulatory requirements
- **Bring** Operational processes
- **Bring** Scientific requirements
- **Collaborate on a solution**



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Security System Objectives

Define

- **What are you trying to secure?**
 - Select Agents
 - ★ Consequence of theft or release
 - ★ Value of the agents and science
 - Expensive equipment?
 - People?
- **What are you trying to do?**
 - Delay Response force arrives BEFORE the agent is accessed
 - Deny The threat cannot get it
 - Deter The threat does not want to get in



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Security System Objectives

Decide

- **What is acceptable?**

- Performance
- Processes
- People
- Cost
- Time



- **What isn't acceptable?**

- What shouldn't the Security System do?
- Failure indicators
- Dollar cost
- Opportunity costs

Security System

Select Agent Regulatory Requirements

- **The main security components**

- Physical Security
- Information Systems Control
- Inventory Control
- Personnel Security
- Incident Response

- **Associated procedures**

- Training
- Records



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Security System

Physical Security

- **An integrated system of physical devices which secures a select agent or toxin**
 - Physical [fence, locked doors, locked freezers, guards]
 - Technological [electronic, bio-metric]
 - Mechanical [locks and keys]
- **Detects a threat action**
- **Alerts the response force**
- **Delays the threat until the response force arrives**



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Security System

Physical Security

- **Advantages**
 - Effective
 - Measurable
- **Disadvantages**
 - Cost initially and overtime
 - Often inflexible
 - Not fail-proof
 - Must be kept up to date



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Security System

Keys to Physical Security

- **Keys**
 - Alarms notify response force capable of defeating the threat
 - Barriers which slow the threat down enough to allow the response force to arrive
 - Be balanced (no weak links)
 - Alert a response force which responds in a predictable fashion
 - Meet all regulatory requirements



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Security System

Keys to Physical Security

- **Shoulds**

- Have features should 'channelize' a threat into an alarmed area
- Have features should create a 'defense in depth'
- Security should take advantage of existing features

- **Nots**

- Barriers before the alarm do not count as delay
- Never violate other regulations
- A barrier that is not observed is not a barrier
- A camera that isn't watched isn't surveillance



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Physical Security Examples

- **Perimeter Barrier** Deters and delays the threat well away from the agent; establishes a crime; delays
- **Alarm** Notifies the response force
- **Doors, windows** Slows but does not stop a threat
- **Intrusion detection** Automated means of triggering alarm (motion sensor, acoustic, etc...)
- **Card Key** Central access/limited verification
- **Card Key and PIN** Central access/good verification



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Security System

Operational Security

- ***Integrated*** processes and procedures that establish and maintain security of inventory
 - Personnel Duties
 - Personnel Responsibilities
 - Inspections
 - Work hours
 - Limited access
- **Identifies a threat through observation of variation of the procedures**
- **Response force is usually intervention**



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Security System

Operational Security

- **Advantages**

- Inexpensive
- Easy to design
- Effective if followed



- **Disadvantages**

- Only effective if followed
- Hard to measure
- Easy to overcome
- Enforcement



Security System

Keys to Operational Security

- **Keys**
 - Be based on existing operational processes
 - Create 'transaction points'
 - Consider the 'Human Factor'
- **Shoulds**
 - Re-enforce other process
 - Not create burdensome processes
- **Nots**
 - Conflict with other operational processes



Security System Inventory

- Integrated processes , procedures and technology that tracks the current amount of select agent or toxin on hand
- Must happen!
- The best “alert” for the insider
- Use existing operational processes
 - If you account for working stock as part of investigation, take advantage of that



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Security System

Keys to Inventory

- **Keys**
 - Be integrated into operational, information and physical security
 - Based on operational security “choke points”
 - Track from inception to destruction
- **Shoulds**
 - Be done as often as necessary based on risk and regulation
- **Notes**
 - Solely a piece of paper



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Security System Information

- **“Deny” focused**
- **Integrated processes , procedures and technology that protects critical information**
 - Locked records
 - Network authentication
 - Encryption (data in motion/data at rest)
 - Firewalls
 - Anti-malicious code (Spyware/Virus)
 - Strong Passwords
- **Identifies a threat through observation of variation**
- **Response force blocks access (automated)**



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Security System Information

- Probably managed by someone else
- Advantages
 - Protects other systems
 - Anonymity is **A VERY POWERFUL** deterrent
- Disadvantages
 - Only effective if followed
 - One time failure can be catastrophic
 - Must be supported by personnel, physical and operational security



Security System

Keys to Information Security

- **Keys**

- Be integrated into operational, personnel and physical security
- Not prevent authorized access to information
- Be legal

- **Shoulds**

- Be based on “need to know”
- Be based on “least privilege”

- **Notes**

- Solely a technological issue



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Security System Personnel

- Security Risk Assessment
- Can you do more?
 - Check with your legal department
- But, give yourself credit for what you are doing
 - Do you check education?
 - Do you check job references?
 - Are additional background checks done?



Security System Balanced

- “Equally” effective security across the system
 - Same strength locks on the doors
 - If one access point is monitored, all are
 - Ground floor windows re-enforced
- Unbalanced Security wastes resources
- Unbalanced Security provides opportunities
- Examples of unbalanced security
 - 1 of 4 doors alarmed
 - Exterior video cameras without security lighting
 - Video camera being used as access control barrier
 - Having a single guard with no provision for lunch
 - Camera operators who don't know what they're looking for
 - Buying security doors but windows that lead directly into that lab not secured



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Response

- Force capable of arriving in time to defeat the threat
- Predictable
 - Memorandum of Agreement (MOA)
 - Tested
- Force capable of defeating the threat
- Can also be layered



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Risk Management

Accepted risk

- You've done all you can
 - You've asked for assistance
 - You've coordinated with everyone
 - You've managed regulations
 - You've factored out 'acts of God'
-
- What's left is the final risk- **is it acceptable?**



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Microsoft Office
cel 97-2003 Worksh



Document

Security Plan Development Aids

- **Code of Federal Regulations, March 18, 2005** [7 CFR 331, 9 CFR Part 121 and 42 CFR 73]
- **BMBL Ver 5 (Page 104)**
- **Select Agents and Toxins Security Information Document, March 8, 2007**
- **Select Agents and Toxins Security Plan Template, March 8, 2007**
- **APHIS/CDC Security Inspection Checklist, June 5, 2007**
- **<http://www.selectagents.gov>**



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Document Elements for Security Plan

- **Risk assessment**
 - What are you trying mitigate?
 - What's left?
- **Physical Security**
 - Perimeter of facility/site if needed
 - Access control
 - Interior security
 - Security planning and operation



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Document

Elements for Security Plan

- **Inventory Control**

- Inventory management
- Inventory data management
- Tracking
- Transfer records

- **Operational Security**

- Documented
- Trained
- Understood + Followed

- **Information Systems**

- Non-electronic information
- IT infrastructure
- Firewalls, anti-virus, password protection
- Computer room laboratory/office
- Data protection



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Document “Shoulds”

- **Response force**
 - Who?
When?
What conditions?
 - Memorandum of Agreement/Understanding if needed
- **Assumptions**
 - What do think is going to happen?
- **Threats models (if used)**



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Document

Incident Response Plans and Testing

- **Incident Response**
 - Written plan specific to the site
- **Testing/Evaluate** Ensure the system is functioning as designed
- **Keys**
 - Assess ALL components of the system
 - Assess during ALL conditions
 - Update system based on assessment
 - Use and revalidate the scenarios

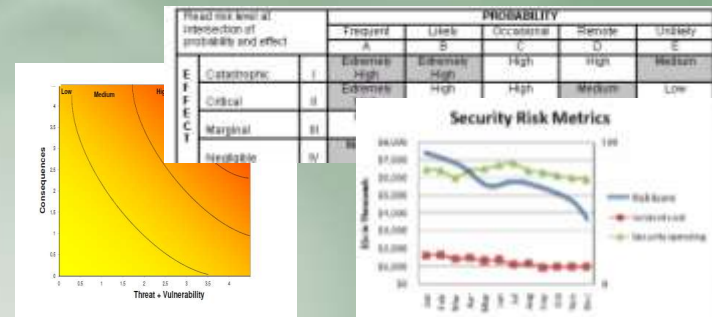


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Conclusion

- Security System Overview
- Risk Management
- Security System Design
- Security Plan
- Incident Response



Questions?



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Break

2:00-2:10



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Security Risk Assessments: Overview, FBI updates, Visitor Movement

2:10-2:55



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Security Risk Assessments – Overview, FBI Updates, Visitor Movement

Sherylyn Roberson

Animal and Plant Health Inspection Service
Select Agent Program

Lori Bane

Centers for Disease Control and Prevention
Division of Select Agents and Toxins

John Strovers

Criminal Justice Information Services Division
Federal Bureau of Investigation



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Federal Partners

42 CFR 73

HHS/CDC
SA Program

USDA
APHIS

7 CFR 331
9 CFR 121

DOJ/FBI CJIS

Security Risk Assessments



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What is a Security Risk Assessment?

- The Security Risk Assessment (SRA) is the method used to approve an individual for access to select agents in accordance with the USA PATRIOT Act of 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- The FBI Criminal Justice Information Services Division (CJIS) conducts the SRA
 - Electronic database and fingerprint check



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USA PATRIOT Act

Public Law 107-56 Signed: 10/23/2001

- Sec. 175b. Possession by Restricted Persons
 - No restricted person shall ship, possess, or receive a Select Agent.



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Security Risk Assessment Prohibited Categories

- A restricted person under 18 U.S.C. 175b (USA PATRIOT Act):
 - is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
 - has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
 - is a fugitive from justice;
 - is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
 - is an alien illegally or unlawfully in the United States;
 - has been adjudicated as a mental defective or has been committed to any mental institution;
 - is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism; or
 - has been discharged from the Armed Services of the United States under dishonorable conditions.



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Security Risk Assessment Prohibited Categories (Bioterrorism Response Act)

- Reasonably suspected by any Federal law enforcement or intelligence agency of:
 - Committing a crime specified in 18 U.S.C. 2332b(g)(5);
 - Having a knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or
 - Being an agent of a foreign power (as defined in 50 USC 1801).



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Who needs a Security Risk Assessment?

- All entities (except for Federal, State, or local governmental agencies)
- The Responsible Official
- The Alternate Responsible Official
- Any owners of non-governmental entities and
- Individuals requesting access to select agents or toxins must have an approved security risk assessment



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Security Risk Assessment Process

- The Responsible Official (RO) requests to update or amend Section 4B table of the APHIS/CDC Form 1 (registration application)
- CDC or APHIS assigns the individual an unique DOJ identifying number
- The individual submits an FD-961 form and fingerprint cards to CJIS
- CJIS conducts the electronic database check
- CDC or APHIS notifies RO of individual's SRA status (approved or restricted)
 - If restricted, CDC or APHIS notifies the RO and the individual



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Security Risk Assessment Process

Job Titles

- **Responsible Official**
- **Alternate Responsible Official**
- **Owner/Controller**
- **Laboratorian** – an individual who performs the work listed in Section 6B, Item #1 and/or directly handles select agents or toxins
- **Support Staff: (*specific role*)** – an individual who provides an indirect service in support of the direct work with select agents or toxins, does not directly handle or work with select agents/toxins, but could potentially gain access to select agents/toxins
- **Visitor** – an individual who has access approval at a registered entity other than yours and will temporarily work with or receive select agent/toxin training at your registered entity



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Security Risk Assessment Process

Job Titles (Support Staff)

- *Examples:*
- Support Staff: IT
- Support Staff: Security
- Support Staff: Administrative
- Support Staff: Animal Care
- Support Staff: Maintenance
- Support Staff: Janitorial



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Avoiding Delays

- Ensure that the information (e.g., name, date of birth, etc.) for individuals listed on the APHIS/CDC Form 1 is identical to the information provided on the FD-961 Form submitted to CJIS for each individual.
- Ensure that the APHIS or CDC assigned DOJ identifier number is correct and listed for Block 11 on the FD-961 Form.
- Ensure all questions are answered on the FD-961 Form.
- Ensure that the applicant signs the front page and third page. The third page is the consent page.
- Send the signed original SRA application materials (e.g., FD-961 form and/or fingerprint cards) to CJIS by way of a traceable carrier (e.g., FedEx, UPS).



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Expediting Security Risk Assessment

- Prior to the request for expedited processing, the Responsible Official should confirm that the FD-961 Form and fingerprint cards have been submitted
- The Responsible Official must submit a written request with justification of good cause to CDC or APHIS. Good cause might be a public health or agricultural emergencies, national security, or a short term visit by a prominent researcher.
- A written decision granting or denying the request will be issued (Refer to 42 CFR 73.10(e), 7 CFR 331.10(e), and 9 CFR 121.10(e)).



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How long is the SRA Valid?

- For individuals that will have access to select agents and toxins:
 - valid for a period of five years
 - can be terminated sooner by the entity, CDC, or APHIS
- For the Responsible Official, Alternate Responsible Official, and individuals that own or control the entity and the entity itself
 - must obtain security risk assessment approval each time the certificate of registration is renewed
 - a certificate of registration is valid for a maximum of three years



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Renewals

Individuals:

- The completed FD-961 form should be faxed to CJIS at 304-625-5393.
- “Renewal” should be written on top of the form because this alerts CJIS that this individual has already been through the SRA process.
- A new DOJ unique identifier number will not be assigned to individuals for renewal SRA requests as long as the individual stays employed with the current registered entity.
- Fingerprint cards are not required for the renewal process, since they are already on file with CJIS; however, CJIS reserves the right to request additional fingerprint cards in the future if necessary.

Entity:

- CJIS conducts security risk assessments of all non-governmental entities.
- The CDC or APHIS Select Agent Program will initiate the SRA for the entity.
- No additional paperwork needs to be submitted to CJIS.



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Change in Employment

- Individual must submit a completed FD-961 form
- Two fingerprint cards are not required if a legible set is already on file
- Access Approval from APHIS or CDC must be granted prior to an individual having access to select agents and toxins at the new place of employment.
- The security risk assessment granted under previous employment is **NOT** transferable.



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Change in Name

- Individual gets married and the last name changes
- Responsible Official submits an amended APHIS/CDC Form 1 that indicates the name change.



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Terminating Individual's Access to Select Agents and Toxins

- Section 10(j) requires that the Responsible Official immediately notify CDC or APHIS when an entity is terminating an individual's access to select agents or toxins.
 - **Name of the individual who is being removed from the entity's registration**
 - **Reasons for termination of access**
 - **Should be submitted in writing via mail, fax, or email**
- Responsible Official must ensure that the individual no longer has the ability to access select agents or toxins.
 - **Retrieving keys**
 - **Changing locks**
 - **Disabling passwords**
 - **Disabling cardkeys**



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Appeal of Restricted Status

- An individual may appeal the decision to deny, limit, or revoke access approval under Section 20 of the Select Agent Regulations
- The appeal must be in writing and must
 - state the factual basis for the appeal
 - Provide supporting documentation and
 - be submitted to the CDC or APHIS within 30 calendar days of the decision
- Where the denial, limitation, or revocation of an individual's access approval is based upon the SRA conducted by CJIS, CDC or APHIS will forward the request for review to the Attorney General.



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Databases Searched

- **Bureau of Immigration and Customs Enforcement's Law Enforcement Support Center databases (Foreign-born candidates):**
 - Central Index System (CIS)
 - Computer Linked Application Information Management System (CLAIMS)
 - Deportable Alien Control System (DACS)
 - National Automated Immigration Lookout System (NAILS II)
 - Nonimmigrant Information System (NIIS)
 - Student and Exchange Visitor Information System (SEVIS)
 - Redesigned Naturalization Application Casework System (RNACS)
 - Refugee, Asylum, and Parole System (RAPS)
 - Enforcement Case Tracking System (ENFORCE)
 - Treasury Enforcement Communications System (TECS)



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Databases Searched

- **National Crime Information Center Files**
 - Foreign Fugitive File
 - Deported Felon File
 - Protection Order File
 - Wanted Person File
 - US Secret Service Protective File
 - SENTRY File (Bureau of Prisons)
 - Convicted Person on Supervised Release File
 - Convicted Sexual Offender Registry
- **Interstate Identification Index: State/Local criminal history**
- **Automated Case Support (ACS): FBI case file database**



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Security Risk Assessment Process

Extra investigative effort put forth in instances of:

- Significant derogatory information in ACS on the individual



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Statistics

Since program inception:

Total processed: 35,993

Unrestricted: 34,496

Restricted: 233

Cancelled: 1,188

Appeals: 74

Sustained 44

Overtured 30



**Select Agent Program
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Restricted Categories for SRAs from CDC-Regulated Entities

(As of 10/21/2008)

<u>Restricted Category</u>	<u>Percentage (%)</u>
Convicted of crime:	71
Under indictment:	6
Fugitive from justice:	6
Adjudicated as a mental defective:	2
Illegal alien:	4
Alien from sensitive country:	1
Dishonorable discharge:	1
Unlawful user of controlled substance:	9
Involvement with terrorism organization:	<1



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Portability of Security Risk Assessments for Visiting Scientists

- Home versus Host Entity
 - Home Entity - place where individual works
 - Host Entity - place where individual visits
- Visitor
 - One-Time Visitor/Short-Term
 - ★ One-time basis
 - ★ Single visit of a limited duration (e.g. training event or less than 30 days)
 - Long-Term (Permanent) Visitor
 - ★ Recurring visits
 - ★ Included in the Host Entity's planned crisis response



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Portability of Security Risk Assessments for Visiting Scientists (Short-Term)

- ★ Host Entity submits request for an amendment to the registration
 - Who is visiting
 - Purpose of the visit
 - Duration of the visit
 - Registered areas that will be visited.
- ★ The visit can be extended beyond the planned duration upon approval by Home Entity and APHIS or CDC.
- ★ APHIS or CDC approves or denies the visit and any deviations to the visit authorization.



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Portability of Security Risk Assessments for Visiting Scientists (Long-Term)

- ★ Host Entity submits request for an amendment to the registration
 - Who is visiting
 - Purpose of the visit
 - Duration of the visit
 - Registered areas that will be visited.
 - Amendment to remove individual once visit is complete
- ★ The Home Entity retains responsibility for the visitor's access approval status and notifies Host entities of a change of individual's status.
- ★ APHIS or CDC approves or denies the visit and any deviations to the visit authorization.



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Portability of Security Risk Assessments for Visiting Scientists (Long-Term)

- The Host Entity is responsible for training the individual per section 15 of the select agent regulations.
- The Host Entity is responsible for maintaining all records outlined in section 17 of the select agent regulations.
- Both Home and Host Entities will report adverse actions to the APHIS or CDC as well as the Home or Host entities.



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Information

Security Risk Assessment Webpage:

<http://www.selectagent.gov/sra.html>

This webpage contains general information on the security risk assessment process including frequently asked questions and a link to the FD-961 form



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Break

2:55-3:00



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Discussion Panel

#2

3:00-3:45



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Closing Remarks and Introduction to Breakout Sessions

3:45-4:00



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Breakout Sessions:

Form 1,

Form 2,

Form 3,

Forms 4 & 5,

CJIS FD-961 Forms,

DHS National Infrastructure Protection Program

4:00-6:00



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